ALOSH for quality, performance, and safety. ALOSH will consider such units for approval when listed by a facility seeking approval under § 37.42 of this subpart.

(g) Roentgenograms shall be given only with equipment having a beam-limiting device which does not cause large unexposed boundaries. The beam limiting device shall provide rectangular collimation and shall be of the type described in part F of the suggested State regulations for the control of radiation or (for beam limiting devices manufactured after August 1, 1974) of the type specified in 21 CFR 1020.31. The use of such a device shall be discernible from an examination of the roentgenogram.

(h) To insure high quality chest roentgenograms:

(1) The maximum exposure time shall not exceed 1/20 of a second except that with single phase units with a rating less than 300 mA at 125 kVp. and subjects with chests over 28 cm. posteroanterior, the exposure may be increased to not more than 1/10 of a second;

(2) The source or focal spot to film distance shall be at least 6 feet;

(3) Medium speed film and medium speed intensifying screens are recommended. However, any film-screen combination, the rated ''speed'' of which is at least 100 and does not exceed 300, which produces roentgenograms with spatial resolution, contrast, latitude and quantum mottle similar to those of systems designated as ''medium speed'' may be employed;

(4) Film-screen contact shall be maintained and verified at 6 month or shorter intervals;

(5) Intensifying screens shall be inspected at least once a month and cleaned when necessary by the method recommended by the manufacturer;

(6) All intensifying screens in a cassette shall be of the same type and made by the same manufacturer;

(7) When using over 90 kV., a suitable grid or other means of reducing scattered radiation shall be used;

(8) The geometry of the radiographic system shall insure that the central axis (ray) of the primary beam is perpendicular to the plane of the film surface and impinges on the center of the film;

(9) A formal quality assurance program shall be established at each facility.

(i) Radiographic processing:

(1) Either automatic or manual film processing is acceptable. A constant time-temperature technique shall be meticulously employed for manual processing.

(2) If mineral or other impurities in the processing water introduce difficulty in obtaining a high-quality roentgenogram, a suitable filter or purification system shall be used.

(j) Before the miner is advised that the examination is concluded, the roentgenogram shall be processed and inspected and accepted for quality by the physician, or if the physician is not available, acceptance may be made by the radiologic technologist. In a case of a substandard roentgenogram, another shall be immediately made. All substandard roentgenograms shall be clearly marked as rejected and promptly sent to ALOSH for disposal.

(k) An electric power supply shall be used which complies with the voltage, current, and regulation specified by the manufacturer of the machine.

(l) A densitometric test object may be required on each roentgenogram for an objective evaluation of film quality at the discretion of ALOSH.

(m) Each roentgenogram made hereunder shall be permanently and legibly marked with the name and address or ALOSH approval number of the facility at which it is made, the social security number of the miner, and the date of the roentgenogram. No other identifying markings shall be recorded on the roentgenogram.

[43 FR 33715, Aug. 1, 1978, as amended at 52 FR 7866, Mar. 13, 1987]

§ 37.42 Approval of roentgenographic facilities.

(a) Approval of roentgenographic facilities given prior to January 1, 1976, shall terminate upon August 1, 1978 unless each of the following conditions have been met:

(1) The facility must verify that it still meets the requirements set forth in the regulations for the second round of roentgenographic examinations (38

FR 20076) and it has not changed equipment since it was approved by NIOSH.

(2) From July 27, 1973, to January 1, 1976, the facility submitted to ALOSH at least 50 roentgenograms which were interpreted by one or more ''B'' readers not employed by the facility who found no more than 5 percent of all the roentgenograms unreadable.

(b) Other facilities will be eligible to participate in this program when they demonstrate their ability to make high quality diagnostic chest roentgenograms by submitting to ALOSH six or more sample chest roentgenograms made and processed at the applicant facility and which are of acceptable quality to the Panel of ''B'' readers. Applicants shall also submit a roentgenogram of a plastic step-wedge object (available on loan from ALOSH) which was made and processed at the same time with the same technique as the roentgenograms submitted and processed at the facility for which approval is sought. At least one chest roentgenogram and one test object roentgenogram shall have been made with each unit to be used hereunder. All roentgenograms shall have been made within 15 calendar days prior to submission and shall be marked to identify the facility where each roentgenogram was made, the X-ray machine used, and the date each was made. The chest roentgenograms will be returned and may be the same roentgenograms submitted pursuant to §37.51.

NOTE: The plastic step-wedge object is described in an article by E. Dale Trout and John P. Kelley appearing in ''The American Journal of Roentgenology, Radium Therapy and Nuclear Medicine,'' Vol. 117, No. 4, April 1973.

(c) Each roentgenographic facility submitting chest roentgenograms for approval under this section shall complete and include an X-ray facility document describing each X-ray unit to be used to make chest roentgenograms under the act. The form shall include: (1) The date of the last radiation safety inspection by an appropriate licensing agency or, if no such agency exists, by a qualified expert as defined in NCRP Report No. 33 (see §37.43); (2) the deficiencies found; (3) a statement that all the deficiencies have been corrected; and (4) the date of acquisition of the X-ray unit. To be acceptable, the radiation safety inspection shall have been made within 1 year preceding the date of application.

(d) Roentgenograms submitted with applications for approval under this section will be evaluated by the panel of ''B'' Readers or by a qualified radiological physicist or consultant. Applicants will be advised of any reasons for denial of approval.

(e) ALOSH or its representatives may make a physical inspection of the applicant's facility and any approved roentgenographic facility at any reasonable time to determine if the requirements of this subpart are being met.

(f) ALOSH may require a facility periodically to resubmit roentgenograms of a plastic step-wedge object, sample roentgenograms, or a Roentgenographic Facility Document for quality control purposes. Approvals granted hereunder may be suspended or withdrawn by notice in writing when in the opinion of ALOSH the quality of roentgenograms or information submitted under this section warrants such action. A copy of a notice withdrawing approval will be sent to each operator who has listed the facility as its facility for giving chest roentgenograms and shall be displayed on the mine bulletin board adjacent to the operator's approved plan. The approved plan will be reevaluated by ALOSH in light of this change.

[43 FR 33715, Aug. 1, 1978; 43 FR 38830, Aug. 31, 1978]

§ 37.43 Protection against radiation emitted by roentgenographic equipment.

Except as otherwise specified in §37.41, roentgenographic equipment, its use and the facilities (including mobile facilities) in which such equipment is used, shall conform to applicable State and Federal regulations (See 21 CFR part 1000). Where no applicable regulations exist, roentgenographic equipment, its use and the facilities (including mobile facilities) in which such equipment is used shall conform to the recommendations of the National Council on Radiation Protection and Measurements in NCRP Report No. 33